

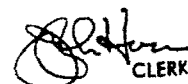
UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH DAKOTA  
SOUTHERN DIVISION

**FILED**

**AUG 26 2013**

UNITED STATES OF AMERICA, )  
)  
Plaintiff, )  
)  
v. )  
)  
DAKOTA LABORATORIES, LLC, a )  
limited liability company, and CHARLES )  
L. VOELLINGER, SR., an individual, )  
)  
Defendants. )

Civil No. 13-4086

  
CLERK

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction (“Complaint”) against Dakota Laboratories, LLC, a limited liability company, and Charles L. Voellinger, Sr., an individual (hereinafter, collectively, “Defendants”), and Defendants having appeared and having consented to entry of this Decree without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and has personal jurisdiction over all parties to this action.
2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the “Act”).
3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that

are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that they have been manufactured, processed, packed, labeled, held, and distributed in violation of current good manufacturing practice (“CGMP”). 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration within the meaning of 21 U.S.C. § 351(a)(2)(B) of articles of drug while such articles are held for sale after shipment of one or more of their components in interstate commerce.

5. For purposes of this Decree, “Defendants’ Facilities” shall refer to 1022 North Main Street, Mitchell, South Dakota, and any future locations at which Dakota Laboratories, LLC, or any successor manufactures, processes, packs, labels, holds, or distributes any article of drug.

6. Upon entry of this Decree, Defendants represent to the Court that Dakota Laboratories, LLC, is not directly or indirectly engaged in the manufacture, processing, packing, labeling, holding, or distribution of any article of drug. Defendants further represent that Dakota Laboratories, LLC, has eliminated all inventory of drugs and that notice of discontinuance of its operations has been communicated in writing to its customers and posted on its website.

7. Upon entry of this Decree, Defendants and each and all of their officers, agents, employees, attorneys, successors, and assigns, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any article of drug at or from Defendants’ Facilities unless and until:

A. Defendants notify the United States Food and Drug Administration (“FDA”) in writing at least ninety (90) calendar days prior to re-entering the business of manufacturing,

processing, packing, labeling, holding, or distributing any article of drug at or from Defendants' Facilities;

B. The facilities, methods, and controls used to manufacture, process, pack, label, hold, and distribute drugs at or from Defendants' Facilities are established, operated, and administered in conformity with CGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

C. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' Facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP expert as soon as they retain such expert;

D. The CGMP expert performs a comprehensive inspection of the facilities, methods, and controls used to manufacture, process, pack, label, hold, and distribute drugs at or from Defendants' Facilities to determine whether they are in compliance with CGMP. This inspection shall include, at a minimum, an evaluation as to whether Defendants have established a comprehensive written quality assurance ("QA") and quality control ("QC") program ("QA/QC program") that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The expert shall determine whether the QA/QC program, at a minimum:

(1) Addresses all facets of compliance monitoring and trend analyses, and internal audit procedures, and confirms that Defendants' Quality Unit is adequately trained and staffed to evaluate CGMP compliance and prevent and correct future deviations from CGMP;

(2) Includes written procedures to ensure that Defendants, in a timely manner, thoroughly investigate (i) product deviations, (ii) reports of complaints about Defendants' products, and (iii) any unexplained discrepancy or failure of a batch of drug or its components to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same drug product and other drug products that may have been associated with the specific discrepancy or failure, and to take required and timely corrective actions for all products that fail to meet their specifications;

(3) Includes written procedures to ensure that Defendants implement and maintain appropriate controls to prevent microbiological contamination of drug products purporting to be sterile, including written procedures to ensure that (i) all aseptic and sterilization processes are validated; (ii) simulation tests (e.g., media fills) are representative of actual filling operations and include worst-case conditions; (iii) operators practice appropriate aseptic techniques; (iv) HEPA filtration systems are adequate to maintain the ISO 5 area; and (v) appropriate environmental monitoring, including trend analysis and investigations, is conducted;

(4) Establishes mechanisms to ensure that written procedures are periodically evaluated to ensure they reflect current and CGMP-compliant practices, and that these procedures provide for all facets of CGMP compliance to be reviewed and controlled by an independent QA unit;

(5) Includes written procedures to ensure that (i) Defendants' QA personnel are promptly notified in writing of all deviations and/or problems that could affect the safety,

identity, strength, quality, and purity of any drug; (ii) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems; and (iii) there are systems to ensure that such written procedures are continuously followed; and

(6) Includes written procedures that specify the responsibilities and procedures applicable to QA and QC personnel, and establishes systems to ensure that such procedures are followed;

E. The CGMP expert certifies in writing to FDA that:

(1) He or she has inspected the facilities, methods, and controls used to manufacture, process, pack, label, hold, and distribute drugs at or from Defendants' Facilities;

(2) All CGMP deviations brought to Defendants' attention since 2010 by FDA, the CGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected; and

(3) Such facilities, methods, and controls are in compliance with the requirements of CGMP. As part of this certification, the CGMP expert shall include a full and complete detailed report of the results of his or her inspection(s);

F. Defendants report to FDA in writing the actions they have taken to:

(1) Correct the CGMP deviations brought to Defendants' attention by FDA, the CGMP expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree; and

(2) Ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs at or from

Defendants' Facilities are operated and will be continuously administered in conformity with CGMP;

G. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, inspects Defendants' Facilities to determine whether the requirements of this Decree have been met, and whether Defendants' Facilities are operating in conformity with CGMP, the Act, and its implementing regulations; and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraphs 7(A)–(F). In no circumstance will FDA's silence be construed as a substitute for written notification.

8. If Defendants have re-entered the business of manufacturing, processing, packing, labeling, holding, or distributing any article of drug at or from Defendants' Facilities in accordance with Paragraph 7, then, after Defendants have complied with Paragraphs 7(A)–(F) and FDA has notified them pursuant to Paragraph 7(H), Defendants shall retain an independent person or persons (the "auditor") who shall meet the criteria described in Paragraph 7(C) to conduct audit inspections of the drug manufacturing operations at Defendants' Facilities no less frequently than once every six (6) months for a period of three (3) years and then annually for a period no less than the following two (2) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 7(H). If Defendants choose, the auditor may be the same person or persons retained as the CGMP expert in Paragraph 7(C).

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with CGMP and identifying any deviations from CGMP ("audit report observations"). As a part of

every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The audit reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than fifteen (15) calendar days after the date the audit inspection is completed. In addition, Defendants shall maintain the audit reports in separate files at their facility and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with CGMP, Defendants shall, within thirty (30) calendar days of receipt of the audit report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the audit report, Defendants believe that correction of the deviations will take longer than thirty (30) calendar days, Defendants shall, within ten (10) calendar days of receipt of the audit report, submit to FDA in writing a proposed schedule for completing corrections ("correction schedule"). The correction schedule must be reviewed and approved in writing by FDA. In no circumstance will FDA's silence be construed as a substitute for written approval. Within thirty (30) calendar days of Defendants' receipt of an audit report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the auditor shall review the actions taken by Defendants to correct the audit report observations. Within fifteen (15) calendar days of beginning that review, the auditor shall report in writing to FDA whether each of the audit report observations has been corrected and, if not, which audit report observations remain uncorrected.

9. Nothing in Paragraph 7 shall preclude Defendants from receiving, holding, or distributing at or from Defendants' Facilities any finished drug products that are in compliance

with the Act and all applicable regulations that Defendants purchase from third parties, so long as:

A. Defendants notify FDA in writing at least forty-five (45) calendar days prior to the first time they receive, hold, or distribute at or from Defendants' Facilities such finished drug products;

B. Defendants do not manufacture, process, pack or label such finished drug products and act only as a distributor of such products; and

C. The third parties who manufacture and supply the finished drug products to Defendants are not owned, controlled by, or otherwise affiliated in any way with Defendants or any of Defendants' officers, directors, agents, representatives, employees, or attorneys.

10. Upon entry of this Decree, Defendants and each and all of their officers, agents, employees, attorneys, successors, and assigns, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly:

A. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Causing any drug to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) while such drug is held for sale after shipment of one or more components in interstate commerce; and

C. Failing to implement and continuously maintain the requirements of this Decree.

11. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report or data prepared or submitted by Defendants, the CGMP expert or the auditor, or any other information, that Defendants have failed to comply

with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including but not limited to ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, processing, packing, labeling, holding, or distributing any or all articles of drug at or from Defendants' Facilities;

B. Recall, at Defendants' own expense, any article of drug that was manufactured, processed, packed, labeled, held, or distributed at or from Defendants' Facilities and that is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information, including analytical results, to FDA if requested; and

E. Take any other corrective actions at Defendants' Facilities or relating to any article of drug manufactured, processed, packed, labeled, held, or distributed at or from Defendants' Facilities, as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

12. The following process and procedures shall apply when FDA issues an order under paragraph 11:

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (i)

Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (ii) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Judicial review of FDA's order shall be made pursuant to paragraph 21.

D. The process and procedures set forth in paragraphs 12 (A)–(C) shall not apply to any order issued pursuant to paragraph 11 if such order states that, in FDA's judgment, the order raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of the order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's

order. Judicial review of FDA's decision under this paragraph shall be made pursuant to paragraph 21.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' Facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to Defendants' Facilities including, but not limited to, all buildings, equipment, in-process and finished materials and products, containers, packaging, labeling, other promotional materials, and other documents and things therein; to take photographs and make video recordings; to take samples of Defendants' in-process and finished materials and products, containers, packaging, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drugs, including components, in order to ensure continuing compliance with the terms of this Decree. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall pay all costs of FDA's inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: \$87.57 per hour and fraction thereof per representative for inspection work; \$104.96 per hour and fraction thereof per representative for analytical or review work; \$0.565 per mile for travel expenses by automobile, government rate or the equivalent for travel by air; and the published government per diem rate

for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. Defendants shall provide notice of this Decree in the following manner:

A. Within five (5) business days of the entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or by certified mail (return receipt requested), to each and all of Defendants' officers, agents, employees, attorneys, successors, assigns, and all persons in active concert or participation with any of them in the manufacture, processing, packing, labeling, holding, or distribution of any article of drug at or from Defendants' Facilities. Within fifteen (15) calendar days of the entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph; and

B. If, after entry of this Decree, any of the Defendants becomes associated with any additional officers, agents, employees, attorneys, successors, assigns, or persons in active concert or participation with any of them, in the manufacture, processing, packing, labeling, holding, or distribution of any article of drug at or from Defendants' Facilities, Defendants shall immediately provide a copy of this Decree, by personal service or by certified mail (return receipt requested), to each such additional person. Within ten (10) calendar days of each time that any Defendant becomes associated with any additional person(s), Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of the additional person(s) who received a copy of this Decree pursuant to this paragraph.

16. Within five (5) calendar days of having notified FDA in writing prior to re-entering the business of manufacturing, processing, packing, labeling, holding, or distributing any article of drug at or from Defendants' Facilities, in accordance with Paragraph 7(A), Defendants shall post a copy of this Decree on a bulletin board in a common area at Defendants' Facilities and shall ensure that the Decree remains posted at each location for as long as the Decree remains in effect.

17. Defendants shall notify FDA in writing, at least fifteen (15) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including relocation, incorporation, reorganization, creation of a subsidiary, dissolution, bankruptcy, assignment, sale or any other change in the structure or identity of Dakota Laboratories, LLC (or any of its parents or subsidiaries), or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least ten (10) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

18. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the Director, Minneapolis District Office, U.S. Food and Drug Administration, 250 Marquette Avenue, Suite 600, Minneapolis, Minnesota 55401, and shall reference this civil action by case name and civil action number.

19. If any Defendant fails to comply with the Act, its implementing regulations, or any provision of this Decree, then Defendants shall pay to the United States of America liquidated

damages in the sum of seven thousand five hundred dollars (\$7,500) per violation for each day such violation continues and an additional sum equal to twice the retail value of each shipment of drugs that violate the Decree, the Act, or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

20. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees, expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to the contempt proceeding.

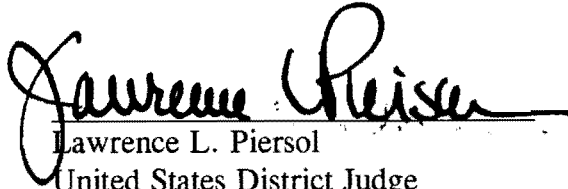
21. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

23. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.


SO ORDERED, this 26<sup>th</sup> day of August, 2013.

BY THE COURT:


  
Lawrence L. Piersol  
United States District Judge


ATTEST:

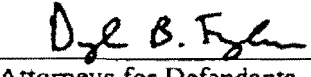
JOSEPH HAAS, CLERK

BY:   
DEPUTY

Entry consented to:  
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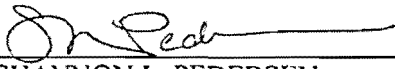
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